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First Named Inventor:	Ivan Osorio		
Application No.:	10/687,344	Group Art Unit:	3769
Filed:	October 15, 2003	Examiner:	Kai Rajan
Title:	SCREENING TECHNIQUES FOR MANAGEMENT OF A NERVOUS SYSTEM DISORDER		

Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT AND RESPONSE TO OFFICE ACTION

Sir:

Applicants respectfully request amendment to the above-identified patent application in response to the Final Office Action of January 31, 2011, in accordance with 37 CFR 1.114. Applicants submit herewith a Request for Continued Examination.

Amendments to the Claims are reflected in the listing of claims beginning on page 2 of this paper.

Remarks begin on page 9 of this paper.

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application. Changes are shown with deletions being designated by strike-through or double-brackets and insertion of new language being underlined.

Listing of Claims:

1. (Currently Amended) A method for performing trial screening with a medical device system, the medical device system providing treatment to a patient with a nervous system disorder producing one or more neurological events, the method comprising:

(a) receiving a first input into at least one processor relating to a location of treatment therapy delivery;

(b) receiving a second input into the at least one processor about a set of therapy parameters that is associated with a treatment therapy;

(c) administering a treatment therapy by the at least one processor in accordance with the first and second inputs; and

(d) receiving a first indication at the at least one processor whether the treatment therapy is within a range of safety and a second indication at the at least one processor whether to utilize the first and second inputs, wherein the second indication is determined by evaluating a criterion, wherein the criterion is selected from a group consisting of a detection frequency of the one or more neurological ~~event~~ events produced by the nervous system disorder, a duration of the one or more neurological ~~event~~ events, an intensity of the one or more neurological ~~event~~ events, and an electrographic spread of the one or more neurological ~~event~~ events.

2. (Currently Amended) The method of claim 1, further comprising:

(e) if the first indication indicates that the treatment therapy is within [[a]] the range of safety and if the second indication indicates that the first and second inputs are to be used, applying the treatment therapy at a future point in time.

3. (Original) The method of claim 1, wherein the nervous system disorder is selected from the group consisting of a disorder of a central nervous system, a disorder of a peripheral nervous system, a mental health disorder, and a psychiatric disorder.

4. (Original) The method of claim 3, wherein the nervous system disorder is selected from the group consisting of epilepsy, Parkinson's disease, essential tremor, dystonia, multiple sclerosis (MS), anxiety, a mood disorder, a sleep disorder, obesity, and anorexia.

5. (Original) The method of claim 1, wherein the treatment therapy is selected from the group consisting of electrical stimulation, magnetic stimulation, drug infusion, and brain temperature control.

6. (Original) The method of claim 1, wherein the treatment therapy is provided to a location of a body selected from the group consisting of a brain, a vagal nerve, a spinal cord, and a peripheral nerve.

7. (Original) The method of claim 1, wherein the medical device system is selected from the group consisting of an external system, a hybrid system, and an implanted system.

8. (Currently Amended) The method of claim 2, further comprising:

(f) ~~in response to step (e),~~ if the treatment therapy applied at the future point in time is not successful, ~~repeating steps (a)-(d),~~ receiving into the at least one processor at least one of a third input and a fourth input, the third input relating to the location of treatment therapy delivery but different from the first input, and the fourth input relating to the set of therapy parameters but different than the second input; and

administering the treatment therapy in accordance with the at least one of the third input and the fourth input.

9.-10. (Cancelled)

11. (Currently Amended) The method of claim 1, wherein the evaluating the criterion ~~in (d)~~ comprises:

(i) obtaining treatment data during the trial screening ~~session~~, wherein the treatment therapy is applied;

(ii) obtaining comparison data during a neurological event screening ~~session~~, wherein the treatment therapy is not applied, and wherein the comparison data correspond to the treatment data;

(iii) deleting a portion of the comparison data corresponding to a blanking interval of the treatment therapy; and

(iv) calculating a difference between the treatment data and the comparison data in order to determine the efficacy of the treatment therapy.

12. (Previously Presented) A non-transitory computer-readable medium having computer-executable instructions for performing the steps recited in claim 1.

13. (Cancelled)

14. (Previously Presented) A non-transitory computer-readable medium having computer-executable instructions for performing the steps recited in claim 11.

15. (Currently Amended) A method for performing neurological event screening with a medical device system, the medical device system providing treatment to a patient with a nervous system disorder producing one or more neurological events, the method comprising:

(a) detecting an occurrence of a neurological event produced by the nervous system disorder by using a set of monitoring elements that obtains a set of neurological signals indicative of the neurological event;

(b) automatically identifying a neurological event focus location that is associated with the neurological event using at least one processor;

(c) reporting information about the neurological event focus location to an output device;

(d) identifying a neurological event spread that is associated with the neurological event using the at least one processor;

(e) reporting the neurological event spread to the output device[[.]];

(f) receiving a first input at the at least one processor about a configuration of a treatment delivery unit that is associated with the neurological event screening;

(g) receiving a second input at the at least one processor about a set of therapy parameters that is associated with a treatment therapy;

(h) administering the treatment therapy by the at least one processor in accordance with the first and second inputs;

(i) receiving a first indication at the at least one processor whether the treatment therapy is within a range of safety and a second indication at the at least one processor whether to utilize the first and second inputs, wherein the second indication is determined by evaluating a criterion characterizing the neurological event; and

(j) if the first indication indicates that the treatment therapy is within a range of safety and if the second indication indicates that the first and second inputs are to be used, administering the treatment therapy by the at least one processor at a future point in time.

16. (Previously Presented) The method of claim 15, further comprising:

(k) providing a recommendation from the at least one processor for the configuration of a treatment delivery unit and the set of therapy parameters to an output device.

17. (Previously Presented) A non-transitory computer-readable medium having computer-executable instructions for performing the steps recited in claim 15.

18. (Currently Amended) A medical device system for performing neurological event screening, the medical device system providing treatment therapy to a patient with a nervous system disorder producing one or more neurological events, the medical device system comprising:

a set of monitoring elements that obtains a set of neurological signals indicative of a neurological event, wherein each monitoring element receives a neurological signal;

means for providing a first input relating to a location of treatment therapy delivery and a second input relating to a set of therapy parameters associated with the treatment therapy;

an output device; and

a processor that is coupled to the at least one monitoring element and to the output device, the processor configured to:

(a) detect an occurrence of a neurological event produced by the nervous system disorder with a detection algorithm;

(b) identify at least one neurological event focus location that is associated with the neurological event;

(c) store the neurological event focus location as stored information; and

(d) receive a first indication whether the treatment therapy is within a range of safety and a second indication whether to utilize the first and second inputs, wherein the second indication is determined in accordance with a criterion selected from a group consisting of a detection frequency of the neurological event, a duration of the neurological event, an intensity of the neurological event, and an electrographic spread of the neurological event, whereby if the treatment therapy is within [[a]] the range of safety and the first and second inputs are to be used, administer the treatment therapy at a future point in time in a closed loop mode or an open loop mode.

19. (Previously Presented) The medical device system of claim 18, wherein the processor is configured to use the output in (b) to:

(i) determine a first channel that is associated with an earliest onset of the neurological event, the first channel corresponding to a first neurological signal.

20. (Previously Presented) The medical device system of claim 18, wherein the processor is further configured to:

(e) determine whether to perform algorithm adaptation; and

(f) compute threshold and time duration constraint settings that are associated with the detection algorithm, in response to (e).

21. (Currently Amended) A medical device system for performing trial screening, the medical device system providing treatment to a patient with a nervous system disorder producing one or more neurological events, the medical device system comprising:

a treatment therapy unit that delivers treatment therapy to the patient;

a set of monitoring elements that obtains a set of neurological signals indicative of a neurological event produced by the nervous system disorder, wherein each monitoring element receives a neurological signal;

an input device that obtains input information from a user;

an output device that presents output information to the user; and

a processor that is coupled to the treatment therapy unit, the set of monitoring elements, the input device, and the output device, the processor configured to:

(a) receive a first input relating to a location of treatment therapy delivery;

(b) receive a second input about a set of therapy parameters that is associated with a treatment therapy;

(c) administer the treatment therapy in accordance with the first and second inputs;

(d) receive a first indication whether the treatment therapy is within a range of safety and a second indication whether to utilize the first and second inputs, wherein the second indication is determined in accordance with a criterion, wherein the criterion is selected from a group consisting of a detection frequency of the neurological event, a duration of the neurological event, an intensity of the neurological event, and an electrographic spread of the neurological event; and

(e) if the first indication indicates that the treatment therapy is within [[a]] the range of safety and if the second indication indicates that the first and second inputs are to be used, administer the treatment therapy at a future point in time, wherein the treatment therapy is applied in a closed loop mode or an open loop mode.

22. (Currently Amended) A method for performing trial screening with a medical device system, the medical device system providing treatment to a patient with a nervous system disorder producing one or more detection clusters, the method comprising the steps of:

(a) receiving a first input into at least one processor relating to a location of treatment therapy delivery;

(b) receiving a second input into at least one processor about a set of therapy parameters that is associated with a treatment therapy;

(c) administering the treatment therapy by the at least one processor in accordance with the first and second inputs, wherein the administering of the treatment comprises:

(i) applying the treatment therapy every n^{th} detection cluster;

(d) receiving a first indication at the at least one processor whether the treatment therapy is within a range of safety and a second indication at the at least one processor whether to utilize the first and second inputs, wherein the second indication is in accordance with an evaluation of a criterion, the evaluation comprising:

(i) obtaining treatment data by the at least one processor for a first detection cluster produced by the nervous system disorder, wherein the treatment therapy is applied;

(ii) obtaining comparison data by the at least one processor for a second detection cluster produced by the nervous system disorder, wherein the treatment therapy is not applied, and wherein the comparison data correspond to the treatment data;

(iii) deleting a portion of the comparison data by the at least one processor corresponding to a blanking interval of the treatment therapy; and

(iv) calculating a difference by the at least one processor between the treatment data and the comparison data in order to determine the efficacy of the treatment therapy; and

(e) if the first indication indicates that the treatment therapy is within [[a]] the range of safety and if the second indication indicates that the first and second inputs are to be used, administering the treatment therapy at a future point in time.

23. (Previously Presented) The method of claim 22, wherein the nth cluster is at least a 2nd cluster, whereby the treatment therapy is not administered by the at least one processor to at least every other cluster.

Remarks

Applicants have reviewed the Final Office Action mailed January 31, 2011. Claims 1-8, 11, 12, and 14-23 are pending. By this amendment, claims 1, 2, 8, 11, 15, 18, 21 and 22 are amended. Applicants respectfully submit the following remarks and request reconsideration.

As a preliminary matter, Applicants respectfully request that the Examiner more explicitly describe the grounds of rejection for claims 14-23. In the Office Action the Examiner simply stated that "Claims 14-23 are rejected on substantially the same basis as claims 1-8, 11, and 12 above, by Shaw et al." (Office Action, p. 6, lines 1-2). However, claims 14-23 include several limitations in addition to and/or different from the limitations in claims 1-8, 11, and 12, and it is unclear how the Examiner believes Shaw anticipates these claims because the discussion of claims 1-8, 11, and 12 does not mention these additional/different limitations. Applicants respectfully note that a "plurality of claims should never be grouped together in a common rejection unless that rejection is equally applicable to all claims in the group." MPEP 707.07(d). *See also* 37 CFR 1.104 (b), "When a reference is complex or shows or describes inventions other than that claimed by the applicant, the particular part relied on must be designated as nearly as practicable. The pertinence of each reference, if not apparent, must be clearly explained and each rejected claim specified." Accordingly, Applicants respectfully request the Examiner provide further details as to the grounds of rejection for claims 14-23.

Claim Rejections Under 35 U.S.C. § 102

Claims 1-8, 11, 12, and 14-23 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Patent No. 6,014,587 issued to Shaw et al. ("Shaw").

Applicants respectfully traverse the rejection because Shaw does not disclose all the limitations of the claims. To show anticipation under 35 U.S.C. § 102, an examiner "must show that each element of the Claim in issue is found, either expressly or under principles of inherency, in a single prior art reference, or that the claimed invention was previously known or embodied a single prior art device or practice." *Minnesota Mining & Manufacturing Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1565 (Fed. Cir. 1992). *See also* MPEP § 2131. Although Applicants reserve the right to pursue the previously presented and originally

filed claims in future prosecution, Applicants have amended the claims to further define the claimed invention, and more quickly advance the current prosecution. To the extent the current rejection applies to the amended claims, Applicants respectfully submit that Shaw does not disclose or otherwise suggest all of the limitations of the claims as amended. In addition, Applicants respectfully submit that there is no convincing line of reasoning for a finding of obviousness in place of the undisclosed limitations.

Independent Claim 1

Claim 1 provides a method for performing trial screening with a medical device system that provides treatment to a patient with a nervous system disorder producing one or more neurological events. Among other things, the method includes receiving first and second inputs, administering a treatment therapy, and receiving a first indication and a second indication at the at least one processor. In particular, the second indication indicates whether to utilize the first and second inputs and is determined by evaluating a criterion. The criterion is selected from a group consisting of a detection frequency, a duration, an intensity, and an electrographic spread of the one or more neurological events produced by the nervous system disorder.

In the Final Office Action, the Examiner stated that Shaw at column 29, lines 41-49 and column 30, lines 31-40 disclosed the elements of claim 1, part (d). Office Action, p. 3, lines 5-13. Applicants respectfully disagree with the Examiner's characterization and submit that Shaw at least does not disclose (1) receiving a second indication as to whether to use a first input relating to a therapy delivery location, and (2) that the second indication is determined by evaluating a criterion selected from a detection frequency, duration, intensity, or electrographic spread of one or more neurological events produced by a nervous system disorder.

With regard to (1), the cited sections of Shaw at least do not disclose receiving an indication whether to use an input relating to a therapy delivery location as claimed. In the Office Action, the Examiner appeared to suggest that the "pulse parameters input into the system" in Shaw somehow disclose an indication whether to use an input relating to a therapy delivery location. Applicants respectfully submit, though, that the "pulse parameters" cited by the Examiner are not related to a therapy delivery location as claimed, but instead are "specified by the user via the front panel." Col. 29, lines 40-41.

With regard to (2), the Examiner stated that "[f]urthermore, level and magnitude of seizures is measured and monitored for determining the appropriate treatment required." Office Action, p. 3, lines 12-13. However, the portion of Shaw cited by the Examiner (e.g., col. 29, line 30 to col. 30, line 66) describes monitoring parameters of electroconvulsive therapy (ECT) treatments, not evaluating a criterion characterizing a neurological event produced by a nervous system disorder such as a detection frequency, duration, intensity, or electrographic spread of a neurological event produced by a nervous system disorder as claimed. In other words, claim 1 provides for receiving a second indication (whether to utilize the first and second inputs) that is determined by evaluating a criterion that characterizes one or more neurological events produced by a nervous system disorder. Shaw instead determines if an ECT treatment output meets desired specifications in order to terminate the treatment if any one of these parameters deviates from specified or predetermined values of these parameters. Col. 29, lines 39-47. To do so, Shaw describes several "hardware self-tests" (listed in col. 29, Table 2) that monitor the treatment output to be sure it meets desired specifications.

Accordingly, Applicants submit that Shaw does not disclose all of the limitations of independent claim 1 and respectfully request that the rejection be withdrawn. Applicants also submit that there is no convincing line of reasoning for a finding that it would obvious to modify Shaw to include the undisclosed limitations. Claims 2-8, 11, 12, and 14 depend from claim 1 and thus are believed to be patentable for at least the reasons presented above with respect to claim 1.

Independent Claims 15, 18, 21, and 22

Amended claims 15, 18, 21, and 22 include limitations similar to those discussed above with respect to claim 1, and thus are believed to be patentable over Shaw for at least the reasons presented above for claim 1. Applicants also submit that Shaw does not disclose several other limitations in claims 15, 18, 21, and 22. For example, claim 15 provides a method that includes, in part, identifying a neurological event focus location and a neurological event spread and reporting information about the location and spread to an output device. Claim 15 also provides for receiving a first input about a configuration of a treatment delivery unit. Claim 18 provides a medical device system with, among other things, a processor configured to identify and store a

neurological event focus location. Claim 21 provides a medical device system for performing trial screening including, among other things, a processor configured to receive an input relating to a location of a treatment therapy delivery, to receive a second indication whether to utilize first and second inputs, and administer the treatment therapy at a future point in time in a closed loop mode or an open loop mode. Claim 22 provides a method for performing trial screening including, among other things, that evaluating a criterion for the second indication includes obtaining treatment data for a first detection cluster, obtaining comparison data for a second detection cluster, deleting a portion of the comparison data, and calculating a difference between the treatment data and the comparison data to determine the efficacy of the treatment therapy. Applicants respectfully submit that Shaw does not disclose at least these additional limitations. As noted above, the Office Action also does not indicate where Shaw discloses these additional limitations. Accordingly, Applicants respectfully submit that independent claims 15, 18, 21, and 22 are patentable over Shaw for at least the reasons presented above with respect to claim 1 and for at least these additional reasons discussed immediately above. Claims 16-17 depend from claim 15, claims 19-20 depend from claim 18, and claim 23 depends from claim 22, and thus these claims are also believed to be patentable for at least the same reasons. Thus, Applicants respectfully request the rejection over Shaw be withdrawn.

Conclusion

Applicants submit that this application is in condition for allowance for at least the reasons presented above. Favorable consideration and prompt allowance of the application are respectfully requested. The Commissioner is authorized to charge any deficiencies and credit any overpayments to Deposit Account No. 06-1910. The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted,

/Michael J. Feller/

Dated: April 29, 2011

Michael J. Feller
Registration No. 59,296

Customer No. 81390
FREDRIKSON & BYRON, P.A.
200 South Sixth Street, Suite 4000
Minneapolis, MN 55402-1425 USA
Telephone: (612) 492-7000
Facsimile: (612) 492-7077

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